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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,764

04/17/2006

Gary Steven Ungless

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EXAMINER

GEDEON, BRIAN T

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

07/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,764	Applicant(s) UNGLESS ET AL.	
	Examiner Brian T. Gedeon	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-27, 31, 33, 36, 37 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-27, 31, 33, 37 and 39-46 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Specifically, the oath/declaration do not have the correct statement with respect to the duty to disclose.

CORRECT STATEMENTS should read:

- "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

INCORRECT STATEMENTS:

- "I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)"
- "I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)"
- "I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations Section 1.56"

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is indefinite with regard as to what position in Applicant defines as "vertical movements."

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 23, 25, 31, 39, 42, 45, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohtake (US Patent no. 5,483,967).

In regard to claims 23, 25, 42, 45, and 46, Ohtake describes a bioelectrical signal (e.g., ECG signals, col 2 lines 49-55) recording device that includes a base member 2 which has an adhesive side 3 that serves to adhere the base member to the body of a patient, col 2 lines 55-60. The base member 2 also includes biopotential electrodes 11. An embodiment of the device can employ a single electrode 11, as depicted by reference numeral 21 of figure 1, col 4 lines 51-55. The base member 2 necessarily

Art Unit: 3766

includes support means, since recording element 15 is mounted upon it. The recording element 15 is interpreted to be an equivalent to the monitor and includes an integrated circuit for receiving and processing sensed cardiac signals, col 3 lines 42-50. The recording element 15 is used to record and store the electrical signals picked up by the electrodes 11. Electrical communication lines 16 are the means for coupling to the recording unit 15 at least a second electrode 11, col 3 lines 57-59.

Further in regard to claims 42, 45, and 46, it can be seen in figure 1 of Ohtake that the recording element 15 (i.e., monitor) has a maximum lateral dimension less than or equal to the maximum lateral dimension of the ECG electrode base member, thereby the recording element does not extend beyond the outer edge of the electrode base. The same is true when the electrode base is embodied as described by reference numeral 21 of figure 1.

In regard to claim 24, electrical communication lines 16 are the means for coupling to the recording unit 15 at least a second electrode 11, col 3 lines 57-59, and are interpreted as being an equivalent to the coupling means.

In regard to claim 31, Ohtake has a memory unit 25 for storing the ECG signals picked up by the electrodes, col 5 lines 35-39.

In regard to claim 39, the method as claimed is anticipated by Ohtake since Ohtake discloses a device for measuring ECG biopotential signals, which can be embodied as a single electrode sensor, as depicted by reference numeral 21 of figure 1, col 4 lines 51-55. Recording element 15 has an integrated circuit for ascertaining,

processing, and storing the biopotential signal data, col 3 lines 42-50 and col 5 lines 35-39.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 26, 27, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohtake (US Patent no. 5,483,967).

In regard to claims 26 and 27, Ohtake discloses the claimed invention with the exception of specific dimensions for the maximum lateral dimensions of the ECG electrode or of the monitor. It would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize 55 mm or less and 35 mm or less for the maximum lateral dimensions since our reviewing courts have held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

In regard to claim 41, the recording element 15 is attached to one side of the base member 2. Ohtake does not describe as being either rotatable nor being non-rotatable. However, the Examiner considers it to not be beyond one of ordinary skill in the art at the time the invention was made to immovably fix the recording element to the electrode base.

8. Claims 33, 37, 40, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohtake (US Patent no. 5,483,967), in view of Kristbjarnarson (US Patent no. 6,049,730).

In regard to claims 33, 37, 40, 43, and 44, Ohtake describes the invention as claimed except for the use of an accelerometer to generate movement data. Kristbjarnarson, in a similar field of endeavor, discloses an external monitor 10 for monitoring a user's heart, figures 5 and 8, comprising: a cardiac sensor 13; an accelerometer (inclinometer containing accelerometer sensors) 16; a support means (harness, not labeled in fig. 8) for securing the cardiac sensor and the accelerometer in position for sensing the user's heart beat and movement (see col. 9, lines 9-20); and a processor (recording equipment) 12 coupled to the cardiac sensor and the accelerometer for generating cardiac data 20 and movement data 22 (see col. 6, lines 20-32). The monitor system is externally mounted to the patient. Also, the accelerometer 16 is capable of measuring in any of the three dimensions, figure 5. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Ohtake with an accelerometer, since Kristbjarnarson teaches that it is known in the art to include an activity or movement

Art Unit: 3766

sensor such as an accelerometer in an ambulatory physiological recorder.

Further in regard to claims 43 and 44, the monitor 10 of Kristbjarnarson includes a processor 12/32 to process signals it receives from the electrodes 13 according to a predetermined parameter in order to generate the cardiac data and modifies that parameter in response to signals it receives from the accelerometer (see col. 8, lines 5-25).

Response to Arguments

9. Applicant's arguments, see Remarks, filed 30 April 2007, with respect to the rejection(s) of claim(s) 23-25, 31-34, and 36-39 under Del Mar et al. (US Patent no. 6,117,077) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Ohtake (US Patent no. 5,483,967).

10. The Examiner would also like to acknowledge the error, as pointed out by Applicant, in regard to claim 34 in the last Office action. The last action incorrectly rejected claim 34 under 35 U.S.C. 102(b) as anticipated by Del Mar et al., while also objecting the claim as being allowable but dependent on a rejected independent claim. Claim 34 should only have been objected to as being allowable but dependent on a rejected independent claim.

Allowable Subject Matter

11. The indicated allowability of claims 43 and 44, claims 34 and 35 as originally presented, is withdrawn in view of the newly discovered reference(s) to Ohtake (US Patent no. 5,483,967), in view of Kristbjarnarson (US Patent no. 6,049,730). Rejections based on the newly cited reference(s) are presented above.

12. Claim 36 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to teach the use of the same set of electrode contacts for making contact to biopotential electrodes as well as for making contact with an interface for transferring data from and/or to the monitor, and/or for resetting or programming the monitor and/or for recharging a battery for powering the monitor.

Conclusion

13. In view of the new grounds of rejection, this action is made **NON-FINAL**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

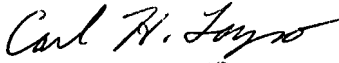
Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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